U.S. Patent Application No.: 10/685,685

Filing Date: October 15, 2003

First Named Inventor: Anthony Costa

## Amendments to the Specification

Please insert the following new paragraph before the field of invention, paragraph [0001]:

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority on U.S. provisional application no. 60/418,726, filed on October 17, 2002, now expired. All documents above are herein incorporated by reference.

Please replace paragraph [0011] with the following amended paragraph:

NM 108

[00]1] The polymer may be polyurethane, more specifically a nonionic hydrophobically modified ethoxylated polyurethane. In a specific embodiment it is a polyethylene glycol-150/decyl alcohol/saturated dicyclohexyl-methane diisocyanate (SMDI) copolymer, sold under the trademark ACULYN Aculyn 44<sup>TM</sup>.

Please replace paragraph [0015] with the following amended paragraph:

NM 108

[00]5] A concentration of about 15 % (w/w) <u>ACULYN</u> Aculyn 44<sup>TM</sup> is adequate to achieve the desired viscosity. Besides the polymer, the gel may further comprise 32-45 % glycol-comprising phase and 40-53 % aqueous phase. The glycol phase comprises the oil and surfactant components, or more hydrophilic components.

Please replace paragraph [0017] with the following amended paragraph:

2/21/08

ACULYNAeulyn 44[[]]<sup>TM</sup> 15 %, ethoxydiglycol 34-45 %, oil[[,]] 1-5 %, polysorbate 20 (sold under the trademark LIPOSORB Liposorb L-20 TM) 1-6 %, demineralised water 41.17 %, propyl gallate 0.1 %, sodium metabisulfite 0.25 %, sodium carbonate 0.05 % and dye yellow 5 LK (14-16%) 0.50 %. In a specific embodiment, the oil was Sweet Birch oil.

Please replace paragraph [0034] with the following amended paragraph:

a polymer which is a consistency modifier admixed to the oil, water or aqueous solution. ACULYN Aculyn 44<sup>TM</sup> is a specific example of such of polymer. It is a nonionic rheology modifier based upon Hydrophobically modified Ethoxylated Urethane (HEUR) chemistry, providing benefits to formulations like thickening, stabilization and suspension. The polymer further contributes to adherence to skin,

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> mucus or mucosa. Any other polymer biologically compatible with epithelial surfaces and having a consistency modifier capacity equivalent to that of ACULYN Aculyn 44<sup>TM</sup>, and more specifically to 15% ACULYN Aculyn 44™, is considered to be within the scope of this invention.

Please replace paragraph [0036] with the following amended paragraph:

1/21/08

[0036]

15 % ACULYN Aculyn 44TM

Please replace paragraph [0049] with the following amended paragraph:

1/21/08

[0049]

(1) 3 g LIPOSORB Liposorb L-20<sup>TM</sup> (polysorbate 20)

Please replace paragraph [0051] with the following amended paragraph:

Please replace paragraph [0052] with the following amended paragraph:

7/21/08

[0051]

(3) 37.4 g ethoxydiglycol (sold under the trademark TRIVALIN Trivalin SF<sup>TM</sup>) (ethoxydiglycol).

1/21/08

[0052]In a separate suitable container equipped with an appropriate mixer add <u>LIPOSORB</u> Liposorb L-20<sup>TM</sup> then add the Sweet Birch oil with mixing. Mix till all the Sweet Birch oil has gone in solution. Then add TRIVALIN Trivalin SFTM and mix till Homogeneous. The proportions of (1), (2) and (3) may be varied from 1-6 %, 1-5 % and 34-45 %, depending on the oil content and hydrophobicity. When no lipid is added, the surfactant and ethoxydiglycol contents are decreased so as to reach a viscosity of about 50 centipoises.

1/21/08

Please replace paragraph [0054] with the following amended paragraph:

Add 15 g ACULYN Aculyn TM \*and mix until

homogeneous liquid gel is obtained. Mix for another 10 minutes or so.

Please replace paragraph [0055] with the following amended paragraph:

1/11/08 [0055] \*ACULYN's Aculyn's 44TM composition: modified polyethylene glycol 34-36%, propylene glycol 38-40 % and water 25-27 %; purchased from Rohm and Haas Company.